

## **DRAWINGS**

The attached sheet of drawings includes changes to Fig. 9. This sheet, which includes Figs. 8 and 9, replaces the original sheet including Figs. 8 and 9.

Figure 9 has been revised to include a reference numeral 69 and the lead line for the reference numeral.

An annotated sheet showing changes to drawing Fig. 9 is attached hereto for the Examiner's convenience.

ATTACHMENTS: Replacement Sheet  
Annotated Sheet Showing Changes

**REMARKS**

In amended Figure 9, reference numeral 69 has been added

Claims 1-20 and 22-55 are currently pending in this application. By this Amendment, claim 21 is canceled, claims 1-2, 24-26, 30 and 43-46 have been amended.

**1. Objections**

Claim 46 and figure 9 are objected for informalities. Claim 46 included a typographical error “an n open position” that has been corrected to “an open position”. The reference number 69 has been added to figure 9. Accordingly, withdrawal of these objections is requested.

**2. § 112 Rejection of the Claims**

Claims 24-26 have been rejected to as being indefinite under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the subject matter which application regards as the invention. The terms “clamping arms” have been corrected to “clamping jaws” as suggested in the Office Action. Withdrawal of this rejection is respectfully requested.

**3. 35 U.S.C. §102(e) Rejection of the Claims**

**(a) Rezai et al (US20050131506)**

Claims 1-3, 5, 12 and 39 stand rejected under 35 U.S.C. §102(e) as being anticipated by Rezai et al (US20050131506). Applicant reserves the right to argue priority over the Rezai et al patent application but in these remarks will be directed to demonstrating that the Rezai et al document does not show or suggest certain features in one or more of claims 1-3, 5, 12 and 39.

Claim 1 specifies a medical lead having (among other things) a generally flat paddle and an electrode array **“offset along the length of the paddle toward the distal end”** such that the portion of the flat paddle proximal of the electrode array has a length of at least 1-1/2 inches (40mm), whereby the electrode array may be advanced into position for electrical stimulation or sensing with the portion of the flat paddle proximal of the electrode array extending through connective tissue, such as the ligamentum flavum.” (Emphasis added) Rezai et al does not show or suggest such an offset electrode array that provides a proximal portion (at least 1-2/2 inches) of the flat paddle, which may extend through connective tissue, such as the ligamentum flavum. As pointed out in paragraph 7 of this patent application: “Because the edge formed by the

proximal end of the paddle is not pushed through the connective tissue, it does not interfere with repositioning, withdrawing or explanting the medical lead. In addition, the flat features of the paddle may be used to anchor the lead to the connective tissue.”

The addition of the 1-1/2 inch dimension to claim 1 further illustrates this distinction in that the claimed offset will thus be sufficient to allow the portion of the flat paddle proximal of the electrode array extending through connective tissue. The 1-1/2 inch offset dimension is not an obvious matter of design choice. The “obvious” design choice would be the opposite, i.e. not to have such an offset portion so as to avoid the use of additional material and to reduce the surface area of an implanted device.

The Rezai et al document simply does not show or suggest any of these features. In contrast Rezai et al discloses a lead having a mechanism for moving the lead in a direction substantially perpendicular to the longitudinal axis of the lead (midline of the spinal cord). The drawings of the Rezai et al document appear to show the electrode array substantially centered in the proximal/distal direction (e.g., see figure 7) and in any event not offset or displaced in the proximal/distal direction by an amount sufficient to allow “the portion of the flat paddle proximal of the electrode array extending through connective tissue,” as specified in claim 1.

The dependent claims are submitted as further distinguishing over the Rezai et al document. In this regard, the Examiner is requested to point out where in Rezai et al any showing or suggestion is made of an off-center connection of electrodes to conductors, as specified in claim 12, because the undersigned was unable to find anything of relevance in Rezai et al and the Office Action does not provide particulars regarding application of Rezai et al against claim 12.

The rejection of claim 39 as being anticipated by Rezai et al is believed to be in conflict with the following statement at page 9 of the Office Action: “Rezai et al discloses the claimed invention *except for the anchor and two clamping jaws.*” Claim 39 is directed to the clamping jaws of the anchor and thus is clearly not shown or suggested by Rezai et al.

Accordingly, withdrawal of the rejections under 35 U.S.C. §102(e) is respectfully requested.

**4. 35 U.S.C. §103 Rejection of the Claims**

**(a) Rezai et al (US20050131506)**

Claims 7, 13, 15-20 and 30-33 stand rejected under 35 U.S.C. §103 as being unpatentable over Rezai et al (US20050131506). (Claim 21 has been canceled without prejudice or admission.) Of these claims 7, 13 and 15-21 are dependent, either directly or indirectly, upon claim 1, which is patentable over Rezai et al as discussed above.

With respect to claim 13, assembly of an implantable pulse generator (IPG) is not believed to be analogous or relevant to a lead paddle formed by two flat portions and, even if the sake of argument, assembly of an IPG were considered relevant, how would such a device show or suggest the internal features of the flat portion that position the electrode and conductor?

With respect to claim 30, it is believed that the remarks made with respect to claim 1 above would also apply to claim 30 in that Rezai et al does not show or suggest the claimed offset. The 1-1/2 inch offset dimension is not an obvious matter of design choice. The “obvious” design choice would be the opposite, i.e. not to have such an offset portion so as to avoid the use of additional material and to reduce the surface area of an implanted device.

Withdrawal of this rejection is respectfully requested.

**(b) Rezai et al in view of Erickson et al (US6895283), Talalla et al (US4633889), or Meadows et al (US6741892)**

Claims 4 and 29 stand rejected under 35 U.S.C. §103 as being unpatentable over Rezai et al in view of Erickson et al (US6895283). Claim 6 stands rejected under 35 U.S.C. § 103 as being unpatentable over Rezai et al in view of Talalla et al (US4633889). Claims 8-11 stand rejected under 35 U.S.C. § 103 as being unpatentable over Rezai et al in view of Meadows et al (US6741892). Claims 4, 6, 8-11 and 29 are dependent either directly or indirectly upon claim 1, which is believed to be patentable as discussed above, and thus are believed to also be patentable over these documents. Applicant reserves the right to provide further arguments with respect to these claims

Withdrawal of these rejections is respectfully requested.

**(c) Rezai et al in view of King (US6745079)**

Claims 14 and 28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Rezai et al in view of King (US6745079). King is owned by the assignee of this application (Medtronic, Inc.) and is not believed to be available as a reference in accordance with 35 U.S.C. § 103(c)(1), which provides:

“Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.”

Withdrawal of this rejection is respectfully requested.

**(d) Rezai in view of Pohndorf et al (US5746722), Gerber (US6055456) and Cabak et al (US20020082619)**

Claims 22-23, 27 and 34-35 stand rejected under 35 U.S.C. §103as being unpatentable over Rezai in view of Pohndorf et al (US5746722), Gerber (US6055456) and Cabak et al (US20020082619). Issue is taken with this rejection in that none of the cited documents appear to pertain to use of an anchor in engagement *against the flat paddle* of a medical lead, as specified in claims 22-23, 27 and 34-35. Withdrawal of these rejections is respectfully requested.

**(e) Rezai, Pohndorf et al, Gerber, and Cabak et al in view of Hess (US6233488)**

Claims 40-42 and 45-55 stand rejected under 35 U.S.C. §103 as being unpatentable over Rezai, Pohndorf et al, Gerber, and Cabak et al in view of Hess (US6233488). Issue is taken with this rejection in that Hess does not show or suggest a flat paddle extending through the ligamentum flavum or connective tissue, that is, the “proximal end of the paddle remaining on the posterior side of the ligamentum flavum” (claim 40) or “the proximal end of the paddle left extending out from the connective tissue” (claim 51). Because the edge formed by the proximal end of the paddle is not pushed through the connective tissue (or ligamentum flavum), it does not interfere with repositioning, withdrawing or explanting the medical lead. In addition, the flat features of the paddle may be used to anchor the lead to the connective tissue. Withdrawal of these rejections is respectfully requested.

## 5. Allowed Claims

Claims 24-26, 36-38 and 43-44 were indicated as being allowable if rewritten to overcome any applicable 35 U.S.C. §112 and so as not to depend upon a rejected base claim (i.e. in independent form, etc.). Claim 24 has been so written in independent form, and thus the allowance of claim 24 and claims 25 and 26 depending upon claim 24 is requested. Applicant reserves the right to rewrite the other claims later.

## 6. Miscellaneous and Conclusion

In view of the foregoing amendments, Applicants respectfully request reconsideration and allowance of the claims as all rejections have been overcome. Early notice of allowability is kindly requested.

The Examiner is respectfully requested to contact the undersigned by telephone at 763.505.0422 or by E-mail at [steve.bauer@medtronic.com](mailto:steve.bauer@medtronic.com) with any questions or comments.

Please grant any extension of time, if necessary for entry of this paper, and charge any fee due for such extension or any other fee required in connection with this paper to Deposit Account No. 13-2546.

Respectfully submitted,

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